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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,113	03/10/2004	Myron Spector	1194-176	2494

6449 7590 11/21/2007

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EXAMINER	
GUCKER, STEPHEN	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
11/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/796,113	SPECTOR ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5-7,9-11,14-17,19 and 22-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5-7,9-11,14-17,19 and 22-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/07 has been entered.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 is vague and indefinite because the only active process step recited in the claim is "providing" a nerve regeneration tube while the body of the claim recites inherent properties of the nerve regeneration tube. More individual active process steps must be recited in the claim in order to make the metes and bounds of the actual method known because "providing" does not define a method of reconnecting nerve ends in a clear definitive fashion.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 2-3, 5-6, 9-11, 14-17, 19, 22-30 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "'278") in view of Stensaas et al. (US 4,778,467, "Stensaas") and further in view of Shimizu (US 6,090,117). The '278 patent discloses a single sheet of a resorbable sidewall material consisting essentially of a single layer collagen sheet material having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells there through, this sheet material further having a fibrous inner surface opposite the smooth barrier surface (column 1, line 51 to column 2, line 6) derived from collagen membrane peritoneal tissue (column 2, lines 52-60). This single layer collagen sheet material is identified as Bio-Gide ® by the instant specification (page 3, paragraphs 0017 and 0018), and is the same material disclosed in the '278 patent. The '278 patent does not disclose using Bio-Gide ® to form a nerve regeneration tube for connecting nerve ends or methods of using such. Stensaas teaches methods of forming tubes for nerve regeneration (Figures 1 and 3A-3B; column

9, line 60 to column 12, line 31; and column 9, lines 1-16 and column 16, lines 54-66 (Figures 7A-7B)). Stensaas does not teach a nerve regeneration tube for connecting nerve ends having an inner diameter of about 0.5-5mm and a length of about 10-100mm formed from a single collagen sheet of the '278 patent, or a filling material comprised of a mixture of Type I and Type IV collagen, or collagen fibers having a substantially longitudinal orientation with respect to said tube, or a filling material including laminin as a nerve growth stimulant. Shimizu discloses a nerve regeneration tube and methods of using such comprising of at least three sheets of collagen (column 6, line 48 to column 7, line 50) but which is also about 1-8mm in inner diameter with a length about 28-35mm, but can differ according to the length of the severed portion of the nerve and the thickness of the nerve (column 7, lines 19-31; see also a 10mm long tube in Comparative Example 4), thereby meeting the limitations of the instant claims. Shimizu also teaches filling materials for a nerve regeneration tube comprising laminin and Type IV collagen (column 8, lines 40-55) and collagen Type I solution or fibers having a substantially longitudinal orientation with respect to said tube (column 7, line 55 to column 8, line 13; column 8, line 65 to column 9, line 48). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the single sheet collagen material of the '278 patent known as Bio-Gide ® with the teachings of Stensaas to make tubing out of said single sheet collagen material for nerve regeneration because Shimizu teaches the advantages of a collagen nerve regeneration tube with one side smooth that inhibits cell permeation, the other side fibrous to promote biological regrowth, which is also taught by the '278 patent.

Furthermore, a simpler nerve regeneration tube can be produced that uses less material (single sheet as opposed to at least three sheets of collagen as taught by Shimizu), is quicker and easier to produce, and would have the further advantage of economic savings due to lowered costs of production by reducing the need for at least three sheets of collagen to a single sheet of collagen. The combined references also establish a *prima facie* case of obviousness because the collagen material of the '278 patent has desirable features such as a smooth surface to inhibit cell adhesion on the outside with a fibrous surface to support cells on the inside and simply forming a tube out of this two-sided collagen material is *prima facie* obvious given that collagen nerve regeneration tubes were in use at least as way back as the 1980s (see Hentz et al. and Rosen et al. already of record, IDS filed 3/10/04). Finally, the advantageous characteristics of the two-sided collagen material of the '278 patent would suggest to and motivate the ordinary artisan to fashion the collagen material into a tube with a smooth outside and fibrous inside in order to promote axonal regeneration in the interior of the tube as indicated by Shimizu (column 7, line 55 to column 8, line 13; column 8, line 40 to column 9, line 63), and even Stensaas (column 9, lines 60-67) describes the desirability of a neural regeneration tube with a smooth exterior and a rough interior.

Applicant's arguments filed 10/22/07 have been fully considered but they are not persuasive. Both the declaration of Spector and Applicant's arguments are drawn to the making of a neural regeneration tube as described by Shimizu. Both the declaration and the arguments assert that if one uses the procedures of Shimizu, a three layer collagen tube is formed with a compressed smooth collagen interior surface, and not the fibrous

interior surface as recited in the instant claims. However, the instant rejection is drawn to the use of the single sheet collagen material as a first part (the '278 patent), the forming of said single sheet collagen into a neural regeneration tube as taught by Stensaas (not Shimizu) by, for example, simply rolling the sheet into a tube and fastening the leading surfaces together (e.g. around a nerve) as a second part, and then the remaining claim limitations are taught by Shimizu for the advantages set forth above as the third part of the rejection. Because the single collagen sheet material of the '278 patent already possesses a smooth and a fibrous side, the fabrication procedures of Shimizu are not required nor are they used in the formulation of the rejection.

7. Claims 2-3, 5-7, 9-11, 14-17, 19, and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "'278") in view of Stensaas et al. (US 4,778,467, "Stensaas") in view of Shimizu (US 6,090,117) as applied above and further in view of Humes (US 5,429,938) for reasons of record and the following. None of Geistlich or Stensaas or Shimizu teach a mixture of Type I and Type IV collagen in a ratio of about 1:1 for supporting biological activity. Humes does teach the use of Type I and Type IV collagen in about 1:1 ratios to support biological activity (column 3, lines 65-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to employ Humes' ratio of about 1:1 of Type I and Type IV collagen because the other references do not qualitatively teach specific amounts between Type I and Type IV collagen and the artisan would be motivated to look to the Humes reference to supply this missing information if said artisan was actually going to reduce to practice a

combination of Type I and Type IV collagen because such information would be required during fabrication and use of the neural regeneration tube.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883. The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SG

Stephen Gucker

November 13, 2007

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER